Individual Safety Report

3304698-0-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting by health professionals of adverse events and product problems

Page CDER/ CDER

Form Approved: OMB No. 0910-0291 Expires:12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 106200

A. Patient information

1. Patient identifier: [redacted] 4295 In confidence
2. Age at time of event: 46 or Date of birth: [redacted]
3. Sex: ☒ female ☐ male
4. Weight: 184 lbs or ____ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death (mo/day/yr)
   - ☒ life-threatening
   - ☒ hospitalization – initial or prolonged
   - ☒ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other:
3. Date of event (mo/day/yr): 4/24/99
4. Date of this report (mo/day/yr): 6/24/99
5. Describe event or problem

4295: HEPATOTOXICITY
46 YOF who was taking approx #20 to #30 Vicodin ES daily for 6 months for abdominal and back pain. Pt was visiting multiple MDs for Vicodin Rx. Pt stopped X 2 weeks on advice of Psych and then dvlp severe epigastric pain and was adm to OSH where pt was diagnosed with acute liver failure secondary to APAP toxicity. Pt admitted to HUP on 4/24 fpr Liver Transplant and tx to MICU.

6. Relevant tests/laboratory data, including dates

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7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

-NKDA
-Depression, Asthma, Laminectomy

CTU 106200

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 VICODIN ES
   #2
2. Dose, frequency & route used
   #1 #20-30 PO QD
   #2
3. Therapy dates (if unknown, give duration)
   #1 ~6 months
   #2
4. Diagnosis for use (indication)
   #1 Back Pain
   #2
5. Event abated after use stopped or dose reduced
   #1 ☒ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
   #1
   #2
7. Exp. date (if known)
   #1
   #2
8. Event reappeared after reintroduction
   #1 ☐ yes ☐ no ☒ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # (for product problems only)
10. Concomitant medical products and therapy dates (exclude treatment of event)
    Prozac, [illegible]

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address

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ADVERSE EVENT REPORTING SYSTEM

4. Operator of device
   ☐ health professional
   ☐ lay user/patient
   ☐ other:
5. Expiration date (mo/day/yr)
6. model # / catalog # / serial # / lot # / other #
7. If implanted, give date (mo/day/yr)
8. If explanted, give date (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on (mo/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
   [redacted] Pharm
   Phone: [redacted]
2. Health professional? ☒ yes ☐ no
3. Occupation: Pharmacist
4. Also reported to
   ☐ manufacturer
   ☒ user facility
   ☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

FDA Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178